DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2000

Mr. Raymond Riddle
Datex-Ohmeda
Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550

Re: K974562
Evaluation of Automatic Class III Designation - INOvent Delivery System
Dated: January 6, 2000
Received: January 7, 2000

Dear Mr. Riddle:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the nitric oxide delivery apparatus, the nitric oxide analyzer, and the nitrogen dioxide analyzer that are intended for use in administering nitric oxide, measuring nitric oxide, and measuring nitrogen dioxide, respectively. FDA concludes that these devices, and substantially equivalent devices of these generic types, should be classified into class II. This order, therefore, classifies the nitric oxide delivery apparatus, the nitric oxide analyzer, and the nitrogen dioxide analyzer and substantially equivalent devices of these generic types into class II under the generic names: Nitric Oxide Administration Apparatus; Nitric Oxide Analyzer; and Nitrogen Dioxide Analyzer. This order also identifies the special control applicable to these devices.

FDA identifies these generic types of devices as Anesthesiology devices under the following:

21CFR 868.5165, Nitric Oxide Administration Apparatus. The nitric oxide administration apparatus is a device used to add nitric oxide to gases that are to be breathed by a patient. The nitric oxide administration apparatus is to be used in conjunction with a ventilator or other breathing gas administration system.

21CFR 868.2380, Nitric Oxide Analyzer. The nitric oxide gas analyzer is a device intended to measure the concentration of nitric oxide in respiratory gas mixtures during administration of nitric oxide.

21CRF 868.2385, Nitrogen Dioxide Analyzer. The nitrogen dioxide gas analyzer is a device intended to measure the concentration of nitrogen dioxide in respiratory gas mixtures during administration of nitric oxide.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

On January 7, 2000, FDA filed your petition requesting classification of the INOvent Delivery System, which consists of a nitric oxide administration apparatus, a nitric oxide analyzer, and a nitrogen dioxide analzyer, into class II. The petition was submitted under section 513(f)(2) of the act. The request for classification under section 513(f)(2) of the act followed FDA's determination that the devices in your system were not substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, or to any devices which have been reclassified into class I or class II. In order to classify the nitric oxide delivery system into class I or II under 513(f)(2), it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in your original reclassification petition, your premarket notification submission K974562, the panel recommendation of November 22, 1996, and the information developed by FDA to address concerns about delivery and monitoring of this drug, FDA has determined that the INOvent Delivery System intended for use in administering nitric oxide, measuring nitric oxide, and measuring nitrogen dioxide can be classified in class II with the establishment of special controls. FDA believes that class II special controls, in addition to the general controls, provide reasonable assurance of the safety and effectiveness of the device.

The special control developed by the agency is a guidance document, entitled Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen

Dioxide Analyzer. This guidance document identifies the risks associated with these types of devices and contains information that will help manufacturers address those risks. This document is available on FDA's website at http://www.fda.gov/cdrh/ode/1157.pdf.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this type of device must first submit to FDA and receive clearance of a premarket notification that contains information about the nitric oxide delivery components. Your device, which has been classified into class II under 513(f)(2) of the act, will be the predicate for substantial equivalence determinations of other products of this generic type. You may begin marketing your system upon receipt of this order.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this classification order, please contact Joanna H. Weitershausen at 301-443-8609 extension 164.

Sincerely,

Kimber C. Richter

Kimber Richter, M.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health